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In re Application of:

Wolfgang HEIL et al.

Confirmation No.: 7991

Serial No.: 09/757,688

Examiner: L.S. Channavajjala

Filed: January 11, 2001

Group Art Unit: 1615

Title: DROSPIRENONE FOR HORMONE REPLACEMENT THERAPY

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

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- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- ☒ a final rejection under 37 C.F.R. § 1.113;
  - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

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☒ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

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AND is filed on or before payment of the issue fee; AND is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

**STATEMENTS UNDER 37 C.F.R. 1.97(e)**

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

**CITED MATERIALS**

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☒ Copies of the materials listed are attached (except for the foregoing).

**NON-ENGLISH LANGUAGE REFERENCES**

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
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**OTHER INFORMATION**

None

**PAYMENT OF FEES DUE (IF ANY):**

- ☒ A check for \$180.00 covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.
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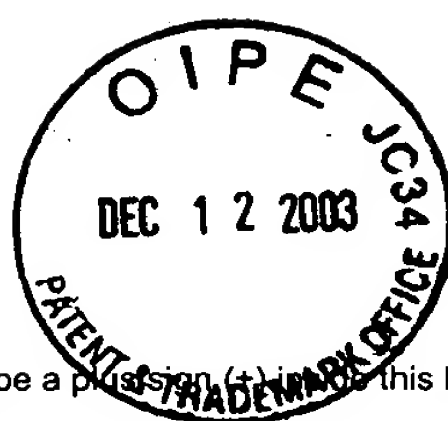
Respectfully submitted,

  
\_\_\_\_\_  
John A. Sopp, Reg. No. 33,103  
Attorney for Applicants

MILLEN, WHITE, ZELANO &  
BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: PLOVIN-2A

Date: December 10, 2003



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Application Number	09/757,688
Filing Date	January 11, 2001
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1615
Examiner Name	L.S. Channavajjala
Attorney Docket Number	PLOVIN-2A

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A1	4,217,347		Horovitz et al.	08-12-1980
	A2	5,001,113		Williams et al.	03-19-1991
	A3	5,569,652		Beier et al.	10-29-1996
	A4	5,583,129		Spona et al.	12-10-1996
	A5	5,824,667		Spona et al.	10-20-1998
	A6	5,827,843		Koninckx	10-27-1998
	A7	6,083,528		Elliesen et al.	07-04-2000
	A8	6,121,465		Mohr et al.	09-19-2000
	A9	6,346,269		Hsiao et al.	02-12-2002
	A10	RE37,564		Spona et al.	02-26-2002

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1	DE	3022337	A1	Eiger et al.	01-07-1982		
	B2	UK	2192542	A1	Upton	01-20-1988		
	B3	WO	95/07081	A1	Koninckx	03-16-1995		
	B4	WO	95/17194	A1	Spona et al.	06-29-1995		
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	B9	WO	98/40069	A2	Klokckers et al.	09-17-1998		

### NON PATENT LITERATURE DOCUMENTS

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	C1	Elstein et al., "Advances in Oral Hormonal Contraception," <i>Zentralbl Gynakol</i> 117 (1995) 559-565	

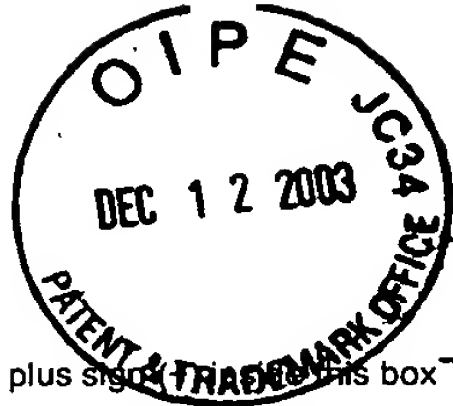
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Sheet

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Attorney Docket Number	PLOVIN-2A

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	C16	Arias et al., "Dissolution properties and in vivo behaviour of triamterene in solid dispersions with polyethylene glycols," <i>Pharm-Acta-Helv</i> , (71, No. 4, 229-35 1996)	
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	C21	Fell et al., "Bioavailability of griseofulvin from a novel capsule formulation," <i>The Journal of pharmacy and pharmacology</i> , 1978 Aug. Vol. 30 (8), p. 479-82	
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	C30	Skouby, (2000) "The rationale for a wider range of progestogens" <i>Climacteric</i> , Vol. 3, (Suppl. 2); 14-20	

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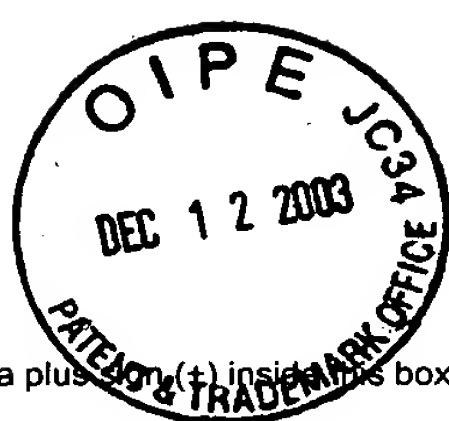
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		Attorney Docket Number	PLOVIN-2A

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	C31	Norman et al., (2000) "Drospirenone" <i>Drugs of the Future</i> 2000, 25(12): 1247-1256	
	C32	R. Krattenmacher, (2000) "Drospirenone: pharmacology and pharmacokinetics of a unique progestogen" <i>Contraception</i> 62, 29-38	
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	C37	"Spirorenone," <i>Drugs of the Future</i> , Vol. 10, No. 6, 1985, pp. 479-481	
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	C41	Rylance et al., "Natural progesterone and antihypertensive action," <i>British Medical Journal</i> , Vol. 290, Jan. 5, 1985, p. 13-14	
	C42	Luotola, "Blood Pressure and Hemodynamics in Postmenopausal Women During Estradiol-17 $\beta$ Substitution," <i>Annals of Clinical Research</i> , Vol. 15, Suppl. 38 1983	
	C43	Mashchak, et al., "Estrogen Replacement Therapy and Hypertension," <i>The Journal of Reproductive Medicine</i> , Vol. 30, No. 10 (Supp)/October 1985, p. 805-810	
	C44	Rajkumar et al., "Hormonal Therapy Increases Arterial Compliance in Postmenopausal Women," <i>JACC</i> , Vol. 30, No. 2, August 1997:350-6	
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	C47	Wren et al., "The effect of type and dose of oestrogen on the blood pressure of post-menopausal women," <i>Maturitas</i> , 5 (1983) 135-142	
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